

GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: November 19, 2012

Submitter: GE Healthcare, GE Medical Systems Ultrasound and Primary

Care Diagnostics, LLC. 9900 Innovation Dr. Wauwatosa, WI 53226

Contact Person: Bryan Behn

Regulatory Affairs Manager

GE Healthcare, GE Medical Systems Ultrasound and Primary

Care Diagnostics, LLC. Phone: 414-721-4214 Fax: 414-918-8275

Device: Trade Name: GE LOGIQ E9 Diagnostic Ultrasound System

Common/Usual Name: LOGIQ E9

Classification Names: Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN

Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO

Product Code: Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Predicate Device(s): K110943, K092271 GE LOGIQ E9 Diagnostic Ultrasound

System

K122327 GE Voluson E6/E8/E8ExpertE10 Diagnostic

Ultrasound System

K113690 GE LOGIQ e Diagnostic Ultrasound System

Device Description: The LOGIQ E9 is a full featured, general purpose diagnostic

ultrasound system which consists of a mobile console approximately 58 cm wide, 86cm deep and 141 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 10-inch LCD touch screen and color 19-inch LCD

image display.

Intended Use: The device is intended for use by a qualified physician for

ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology

(including prostate); Transrectal; Transvaginal; Transesophageal



GE Healthcare

510(k) Premarket Notification Submission

and Intraoperative (abdominal, thoracic, vascular and neurosurgical).

Technology:

The LOGIQ E9 employs the same fundamental scientific technology as its predicate device(s).

<u>Determination of Substantial Equivalence:</u>

Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable medical device safety standards. The LOGIQ E9 and its applications comply with voluntary standards:

- 1. IEC60601-1, Medical Electrical Equipment Part 1: General Requirements for Safety
- IEC60601-1-2,Medical Electrical Equipment Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility
 Requirements and Tests
- 3. IEC60601-2-37, Medical Electrical Equipment —
 Part 2-37:Particular Requirements for the Safety of
 Ultrasonic Medical Diagnostic and Monitoring
 Equipment
- 4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- 5. ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition
- 6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- 7. ISO14971, Application of risk management to medical devices
- 8. NEMA, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)



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The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Final Acceptance testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ E9, did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare considers the LOGIQ E9 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-002

December 18, 2012

Mr. Bryan Behn Regulatory Affairs Manager GE Healthcare 9900 Innovation Drive WAUWATOSA WI 53226

Re: K123564

Trade/Device Name: GE LOGIQ E9 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasound pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: November 19, 2012 Received: November 20, 2012

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE LOGIQ E9 Ultrasound System, as described in your premarket notification:

Transducer Model Number

3CRF	,	M5S-D	RSP6-16-D
6S-D	,	<u>M55-D</u> M6C-D	S1-5
6Tc		ML6-15-D	\$4-10
9L-D		P2D	S4-10-D
11L-D		P6D	<u>C2-9-D</u>
C1-5-D		RAB2-5D	RAB6-D
IC5-9-D		RAB4-8-D	<u>S1-5-D</u>
L8-18i-D		RIC5-9-D	<u>C1-6-D</u>
M4S-D		RNA5-9-D	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA),

it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely Yours,

Janine M. Morris -S

Janine M. Morris
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K123564
Device Name: LOGIQ E9 Diagnostic Ultrasound System
Indications for Use:
The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic, vascular and neurosurgical).
Prescription Use X AND/OR Over-The-Counter Use N/A (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR) (Division Sign Off) Division of Radiological Health Office of In Vitro Diagnostic and Radiological Health

Page 1 of 1

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 Ultrasound System

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode of	Operatio	n			
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic			ļ								
Fetal/Obstetrics[7]	P	Р	P	Р	Р	P	Р	Р	Р	Р	[5,6,9]
Abdominal ⁽¹⁾	P	Р	P	P	Р	P	Р	Р	P	Р	[3,5,6,9]
Pediatric	P	Р	Р	P	Р	Р	Р	P	Р	Р	[3,5,6,9]
Small Organ ^[2]	P	Р	Р	P	Р	P	Р	Р	P.	Р	[3,5,6,9]
Neonatal Cephalic	P	Р	P	Р	Р	Р	Р	Р	Р	Р	[5,6,9]
Adult Cephalic	Р	Р	P	Р	Р	Р	Р	Р	P	P	[5,6,9]
Cardiac Adult	P	Р	P	Р	Р	Р	Р	P	Р	Р	
Cardiac Pediatric	P	Р	Р	Р	Р	P	Р	P	Р	Р	
Peripheral Vascular	Р	P	Р	Р	Р	P	P	P	Р	Р	[3,5,6,9]
Musculo-skeletal Conventional	P	Р	P	Р	Р	Р	Р	Р	. Р	Р	[3,5,6,9]
Musculo-skeletal Superficial	P	Р	P	Р	Р	P	P	P	P	Р	[3,5,6,9]
Other ^[4]	Р	Р	. P	Р	Р	P	Р	P	Р	Р	[3,5,6,9]
Exam Type, Means of Access											
Transesophageal	P	. Р	Р	P	Р	P	Р	P	Р	Р	
Transrectal	P	Р	Р	Р	Р	P	P	P	Р	P	[3,5,6,9]
Transvaginal	Р	Р	Р	Р	Р	P	Р	P	Р	P	[3,5,6,9]
Transurethral											
Intraoperative ^[8]	Р	Р	P	Р	Р	P	Р	P	Р	P	[3,5,6,9]
Intraoperative Neurological	Р	Р	Р	P	Р	Р	Р	P	Р	Р	
Intravascular								<u> </u>			
Laparoscopic				1							

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

5100ki K 123564

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with 3CRF Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

mioridad odo. Diagnostic	Mode of Operation											
Clinical Application Anatomy/Region of Interest	В	м	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]	
Ophthalmic												
Fetal/Obstetrics[7]	P	Р	Р		P	Р	Р	Р	P	Р	[5,6,9]	
Abdominal ^[1]	P	Р	Р		₽	P	Р	Р	Р	Р	[5,6,9]	
Pediatric	Р	Р	Р		P	P	P	Р	Р	P	[5,6,9]	
Small Organ ^[2]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac Adult	<u> </u>								•			
Cardiac Pediatric	<u> </u>											
Peripheral Vascular										•		
Musculo-skeletal Conventional	<u> </u>											
Musculo-skeletal Superficial												
Other ^[4]	Р	Р	Р		Р	P	Р	Р	Р	P	[5,6,9]	
Exam Type, Means of Access												
Transesophageal								,				
Transrectal												
Transvaginal												
Transurethral												
Intraoperative ^[8]												
Intraoperative Neurological						•						
Intravascular									,			
Laparoscopic												

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

5100 K123564

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with 6S-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

~ " · · · · · · · · · · · · · · · · · · ·		. Mode of Operation											
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]		
Ophthalmic													
Fetal/Obstetrics[7]	P	Р	Р	P	Р	Р	Р	Р	P	Р			
Abdominal ^[1]	P	Р.	Р	Р	Р	Р	Р	Р	. Р	Р			
Pediatric	P	Р	Р	P	Р	P	P	Р	Ρ.	Р			
Small Organ ^[2]											•		
Neonatal Cephalic	Р	Р	Р	P	P	Р	Р_	P	·P	Р			
Adult Cephalic	<u>.</u>	<u> </u>	,					<u> </u>					
Cardiac Adult													
Cardiac Pediatric	P	₽.	Р	Р	Р	P	Р	Р	P	Р			
Peripheral Vascular													
Musculo-skeletal Conventional			ļ				ļ <u>-</u>						
Musculo-skeletal Superficial			<u> </u>				ļ						
Other ⁽⁴⁾													
Exam Type, Means of Access		<u> </u>	ļ										
Transesophageal							<u> </u>						
Transrectal													
Transvaginal													
Transurethral							<u> </u>						
Intraoperative ^[8]							L						
Intraoperative Neurological	<u> </u>									<u> </u>			
Intravascular	<u> </u>						<u></u>						
Laparoscopic					,								

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

(PLEASE DO NOT WRITE	E BELOW THIS LINE - (CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Division Stan Off

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K 123,564

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with 6Tc Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

OF 1 1 4 F 15						Mode of	Operation	n			
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic	<u> </u>										
Fetal/Obstetrics[7]											
Abdominal ^[1]	<u>.</u>				ļ						
Pediatric											
Small Organ ^[2]	<u> </u>										
Neonatal Cephalic							<u> </u>				
Adult Cephalic											
Cardiac Adult	Р	Р	P	P	P	Р	Р	Р	Р	Р	
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional	<u> </u>										
Musculo-skeletal Superficial	ļ	L									
Other ^[4]								ļ. <u>.</u>			
Exam Type, Means of Access							<u></u>				
Transesophageal	P	Р	Р	Р	Р	P	Р	P	Р	Р	
Transrectal	<u> </u>	<u> </u>			ļ						
Transvaginal					Ľ						
Transurethral											
Intraoperative ^[8]		<u> </u>									
Intraoperative Neurological											
Intravascular							ļ <u></u>			<u> </u>	
Laparoscopic					l						

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510K K122564

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with 9L-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode of	Operatio	n			
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic		<u> </u>								ľ	
Fetal/Obstetrics[7]	P	P	Р		Р	P	P	Р	Р	Р	[5,6,9]
Abdominal ^[1]	P	Р	Р		P	Р	P	Р	Р	Р	[3,5,6,9]
Pediatric	Р	P	Р		Р	P	P	Р	P	Р	[3,5,6,9]
Small Organ ^[2]	Р	Р	Р		P	P	P	Р	Р	Р	[3,5,6,9]
Neonatal Cephalic											
Adult Cephalic			1								•
Cardiac Adult				L.							
Cardiac Pediatric	<u> </u>										
Peripheral Vascular	Р	P	P		Р	Р	Р	Р	P	Р	[3,5,6,9]
Musculo-skeletal Conventional	Р	Р	Р		P	P	Р	Р_	P	Р	[3,5,6,9]
Musculo-skeletal Superficial	P	Р	Р		Р	P	Р	.р	Р	Р	[3,5,6,9]
Other ^[4]	Р	Р	P		Р	P	Р	Р_	P	Р	[3,5,6,9]
Exam Type, Means of Access								,			
Transesophageal											
Transrectal											
Transvaginal		L .									
Transurethral											
Intraoperative ⁽⁸⁾											
Intraoperative Neurological											
Intravascular											
Laparoscopic			ļ								

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with 11L-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic		ļ	ļ								
Fetal/Obstetrics ^[7]			<u> </u>								
Abdominal ^[1]	· Р	Р	P		Р	Р	Р	P	P	Р	[3,5,6]
Pediatric	P	Р	Р		Р	P	Р	Р	P	Р	[3,5,6]
Small Organ ⁽²⁾	P	P	Р		P	Р	Р	Р	P	Р	[3,5,6]
Neonatal Cephalic		ļ									
Adult Cephalic			<u> </u>								
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	Р	P		Р	Р	Р	Р	P	Р	[3,5,6]
Musculo-skeletal Conventional	P	Ρ.	P		Р	Р	P	P	Р	P	[3,5,6]
Musculo-skeletal Superficial	Р	P	P		Р	P	P	P	P	Р	[3,5,6]
Other ^[4]			<u> </u>					,			
Exam Type, Means of Access			<u> </u>								
Transesophageal			ļ						ļ <u>-</u>		
Transrectal			ļ					ļ	ļ		
Transvaginal					ļ			<u> </u>		\vdash	<u> </u>
Transurethral					ļ		·				
Intraoperative ⁽⁸⁾					<u> </u>						
Intraoperative Neurological					<u> </u>			ļ <u></u>		<u> </u>	
Intravascular	ļ		$oxed{oxed}$								
Laparoscopic	l						<u> </u>				

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- (9) Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123564

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with C1-5-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Interided Ose. Diagnostic	Intended Use. Diagnostic Oltrasound imaging or fluid flow analysis of the numan body as follows.											
Clinical Application	<u> </u>					Mode of	Operatio	n				
Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]	
Ophthalmic	l											
Fetal/Obstetrics[7]	Р	Р	Р	Р	P	Р	Р	P	P	Р	[5,6,9]	
Abdominal ^[1]	Р	Р	Р	Р	P	Р	Р	Р	Р	Р.	[5,6,9]	
Pediatric	Р	P	Р	Р	P	P	Р	Р	Р	Р	[5,6,9]	
Smali Organ ^[2]								,				
Neonatal Cephalic												
Adult Cephalic												
Cardiac Adult				<u></u> .								
Cardiac Pediatric							,					
Peripheral Vascular	Р	Р	Р	P	Р	Р	P	P	Р	Р	[5,6,9]	
Musculo-skeletal Conventional				·								
Musculo-skeletal Superficial										ļ		
Other ^[4]	Р	P	Р	Р	Р	Р	Р	Р	P	P	[5,6,9]	
Exam Type, Means of Access												
Transesophageal												
Transrectal										<u> </u>		
Transvaginal												
Transurethral	<u> </u>	<u></u>										
Intraoperative ^[8]												
Intraoperative Neurological												
Intravascular												
Laparoscopic							,	<u> </u>				

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

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Division of Radiological Health

Office of in Vitro Diagnostics and Radiological Health

510(k) K123564

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with IC5-9-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]	
Ophthalmic	<u> </u>		ļ									
Fetal/Obstetrics[7]	P	P	P		Р	Р	Р	Р	P	Р	[5,6,9]	
Abdominal ^[1]	<u> </u>				ļ					ļļ	·	
Pediatric												
Small Organ ^[2]												
Neonatal Cephalic												
Adult Cephalic	<u> </u>									<u> </u>		
Cardiac Adult								ļ <u>.</u>				
Cardiac Pediatric	ŀ											
Peripheral Vascular												
Musculo-skeletal Conventional											2	
Musculo-skeletal Superficial		ļ									_	
Other ^[4]	P	P	Р		Р	Р	Р	Р	P	P	[3,5,6,9]	
Exam Type, Means of Access	<u> </u>											
Transesophageal										ļļ		
Transrectal	P	Р	Р		Р	Р	P	Р	P	Р	[3,5,6,9]	
Transvaginal	P	P	P		Р	P	Р	P	Р	Р	[3,5,6,9]	
Transurethral		ļ			L							
Intraoperative ⁽⁸⁾							ļ	ļ				
Intraoperative Neurological								L				
Intravascular		<u> </u>										
Laparoscopic												

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with L8-18i-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Interided Ose. Diagnostic	T	bitrasound imaging or fluid flow analysis of the numan body as follows.											
Clinical Application	,					Mode of	Operatio	n			,		
Clinical Application	В	М	PW	CW	Color	Color M	Power	Combined	Harmonic	Coded Pulse	Other [Notes]		
Anatomy/Region of Interest	<u> </u>		Doppler	Doppler	Doppler	Doppler	Doppler	Modes'	Imaging	Puise	[Notes]		
Ophthalmic													
Fetal/Obstetrics ^[7]	<u>.</u>		1										
Abdominal ^[1]		<u> </u>	1										
Pediatric	P	Р	P		P	P	Р	Р	Р	Р	[3,5,6,9]		
Small Organ ^[2]	P	Р	Р		P	P	P	Р	Р	Р	[3,5,6,9]		
Neonatal Cephalic	Р	Р	Р		Р	Р	P	Р	Р	Р	[5,6,9]		
Adult Cephalic													
Cardiac Adult			<u> </u>										
Cardiac Pediatric													
Peripheral Vascular	Р	Р	Р		Р	P	Р	Р	P	Р	[3,5,6,9]		
Musculo-skeletal Conventional	Р	Р	Р		Р	Р	Р	Р	Р	Р	[3,5,6,9]		
Musculo-skeletal Superficial	Р	Р	P		Р	P	Р	P	Р	P	[3,5,6,9]		
Other ^[4]	<u> </u>												
Exam Type, Means of Access													
Transesophageal		ļ	<u> </u>										
Transrectal													
Transvaginal													
Transurethral										L			
Intraoperative ^[8]	Р	Р	P		Р	P	P	. Р	Р	P_	[3,5,6,9]		
Intraoperative Neurological													
Intravascular						:							
Laparoscopic													

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast; testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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510ki K123564

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with M4S-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use: Diagnostic		•					Operation				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic]						<u> </u>				
Fetal/Obstetrics[7]	Р	Р	Р	Р	Р	P	Р	`Р	P	Р	[5,6]
Abdominal ^[1]	P	Р	P	P	Р	P	Р	P	Р	Р	[5,6]
Pediatric	P	P	Р	P	Р	P	Р	Р	P	Р	[5,6]
Small Organ ^[2]	·								-		
Neonatal Cephalic		<u> </u>					ļ <u>.</u>				
Adult Cephalic	P	Р	Р	P	Р	Р	Р	Р	Р	Р	
Cardiac Adult	Р	P	Р	P	Р	P	Р	Р	P	Р	
Cardiac Pediatric									,		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial	<u> </u>										
Other ^[4]			<u>.</u>						<u>.</u>		
Exam Type, Means of Access											
Transesophageal				-							
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic	1										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with M5S-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Interided Use. Diagnostic							Operatio				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											•
Fetal/Obstetrics ^[7]	Р	Р	Р	Р	Р	Р	Р	Р	Р	Р	[5,6,9]
Abdominal ⁽¹⁾	P	P	P	P	Р	Р	P	Р	Р	P	[5,6,9]
Pediatric	Р	P	₽	P	Р	Р	P	Р	P	P	[5,6,9]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	P	P	P	Р	P	P	P	P	P	P	[9]
Cardiac Adult	P	P	Р	Р	P	Р	Р	Р	Р	Р	
Cardiac Pediatric	Р	P	Р	Р	P	P	P	P	Р.	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ⁽⁴⁾											
Exam Type, Means of Access											
Transesophageal											•
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ⁽⁸⁾											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Notes: [1] Abdominal includes Renal, GYN/Pelvic.
 - [2] Small organ includes breast, testes and thyroid
 - [3] Elastography Imaging Elasticity.
 - [4] Other use includes Urology/Prostate
 - [5] 3D/4D Imaging mode
 - [6] Needle guidance imaging
 - [7] Includes infertility monitoring of follicle development
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
 - System provides real-time 3D and 4D acquisition when used with special 4D probes

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Prescription User (Per 21 CFR 801.109)

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Office of In Vitro Diagnostics and Radiological Health

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with M6C-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

intended Use: Diagnostic	Ultras	ouria i	mayin	g or muk	I IIOW a	maiysis	or the m	uman bo	dy as io	ilows.	
Clinical Application						Mode of	Operatio	n			
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal/Obstetrics[7]	Р	P	Р	P	P	P	Р	Р	P	P·	[5,6]
Abdominal ^[1]	P	Р	Р	Р	Р	Р	P	P	Р	Р	[5,6]
Pediatric	P	Р	P	P	P	P	Р	P	Р	Р	[5,6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	<u> </u>										
Cardiac Adult							<u> </u>				
Cardiac Pediatric	<u> </u>										
Peripheral Vascular		<u></u>					ļ				
Musculo-skeletal Conventional		<u> </u>									
Musculo-skeletal Superficial	<u> </u>		,								
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal	<u> </u>										
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic	1										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(K) K123564

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with ML6-15-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

intended Use: Diagnostic	Citias	ouria	iiiagiii	g or nan	2 11044 2		"		dy as io	110443.	
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse*	Other (Notes)
Ophthalmic .											
Fetal/Obstetrics ^[7]						,					
Abdominal ^[1]											
Pediatric	Р	P	P		P	Р	P	Р	P	Р	[3,5,6,9]
Small Organ ^[2]	Р	P	₽		₽	P	Р	Р	Р	Р	[3,5,6,9]
Neonatal Cephalic	P	P	P		P	Р	Р	Р	. P	Р	[9]
Adult Cephalic											
Cardiac Adult	L		<u></u>								
Cardiac Pediatric											
Peripheral Vascular	Р	Р	Р		Р	Р	P	Р	P	Р	[3,5,6,9]
Musculo-skeletal Conventional	Р	Р	P		Р	Р	P	Р	P	Р	[3,5,6,9]
Musculo-skeletal Superficial	P	Р	P		Р	P	Р	Р	Р	Р	[3,5,6,9]
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal			<u> </u>	• _				-			
Transvaginal											
Transurethral	ļ										
Intraoperative ⁽⁸⁾											
Intraoperative Neurological											
Intravascular	ļ			•							
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with P2D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Intended Use: Diagnostic			<u> </u>				Operation				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic	<u> </u>	<u>.</u>									
Fetal/Obstetrics[7]			<u>L</u> .								
Abdominal ^[1]											
Pediatric	<u> </u>	<u> </u>	<u> </u>								
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic			P	Р							
Cardiac Adult	L		Р	Р			•				,
Cardiac Pediatric			Р	P							_
Peripheral Vascular			Р	Р							
Musculo-skeletal Conventional	<u> </u>										
Musculo-skeletal Superficial	<u> </u>										
Other ^[4]				'							
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular										·	
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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Office of In Vitro Diagnostics and Radiological Health

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Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with P6D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

OP 2 LA SPECE						Mode of	f Operatio	n			
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal/Obstetrics ^[7]											-
Abdominal ^[1]		<u> </u>								·	
Pediatric											
Small Organ ^[2]									•		
Neonatal Cephalic											
Adult Cephalic			. Р	Р							
Cardiac Adult			Р	Р							_
Cardiac Pediatric			Р	Р					4		
Peripheral Vascular			Р	P							•
Musculo-skeletal Conventional											_
Musculo-skeletal Superficial											
Other ^[4]					-						
Exam Type, Means of Access	<u> </u>										
Transesophageal											
Transrectal						i					
Transvaginal											_
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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Office of In Vitro Diagnostics and Radiological Health

510(k) K123564

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with RAB2-5D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

interided Use. Diagriostic							i Operatio	-	<u> </u>		
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes'	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic								<u> </u>			
Fetal/Obstetrics[7]	P	Р	P		P	Р	P	Р	Р	Р	[5,6]
Abdominal ⁽¹⁾	P	Р	Р		P	Р	Р	Р	· P	Р	[5,6]
Pediatric	Р	Р	Þ		P	Р	Р	Р	P	Р	[5,6]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric								,			
Peripheral Vascular											
Musculo-skeletal Conventional	Р	Р	P		P	P	P	Р	P	Р	[5,6]
Musculo-skeletal Superficial	<u> </u>										•
Other ^[4]	Р	P	P		P	P	Р	Р	P	Р	[5]
Exam Type, Means of Access	<u> </u>										
Transesophageal	<u> </u>										
Transrectal											
Transvaginal	<u> </u>										
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological									,		
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD,
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with RAB4-8-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application							i Operatio				
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic							<u> </u>				
Fetal/Obstetrics ^[7]	Р	P	Р		p.	P	Р	Р	P	Р	[5,6]
Abdominal ^[1]	Р	P	P		Р	P	Р	Р	P	Р	[5,6]
Pediatric	P	Р	Р		Р	Р	Р	Р	P	Р	[5,6]
Small Organ ^[2]											
Neonatal Cephalic											•
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular							4				
Musculo-skeletal Conventional	Р	Р	Р		Р	P	P	Р	P	Р	[5,6]
Musculo-skeletal Superficial								· · ·			
Other ⁽⁴⁾		<u> </u>									
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[6]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Notes: [1] Abdominal includes Renal, GYN/Pelvic. [2] Small organ includes breast, testes and thyroid
 - [3] Elastography Imaging Elasticity.
 - [4] Other use includes Urology/Prostate
 - [5] 3D/4D Imaging mode
 - [6] Needle guidance imaging
 - [7] Includes infertility monitoring of follicle development
 - [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
 - [9] Volume navigation
 - [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes

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Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with RIC5-9-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

					•	Mode of	Operatio	n			
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal/Obstetrics ^[7]	P	Р	Р	Р	Р	Р	Р	Р	Р	Р	[5,6]
Abdominal ^[1]											
Pediatric	<u> </u>										
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic			L								
Cardiac Adult								ļ			
Cardiac Pediatric											*
Peripheral Vascular						-					
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]	P	P	P	P	P	P	Р	P	P	P	[3,5,6]
Exam Type, Means of Access	<u> </u>		<u> </u>								
Transesophageal											
Transrectal	P	Р	. Ь	P '	P	₽	Р	P	P	P	[3,5,6]
Transvaginal	P	Р	P	P	Р	P	Р	P	Р	P	[3,5,6]
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic		·									

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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Prescription User (Per 21 CFR 801.109)

(Division Sign/Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) 12350

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with RNA5-9-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Interided Ose. Diagnostic	0	ound .	ag	g or man			Operatio		dy do lo	110113.	
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmić	<u> </u>							İ			
Fetal/Obstetrics ^[7]	P	Р	Р	Р	Р	Р	P	Р	Ρ	Р	[5,6]
Abdominal ¹¹	Р	P	Р	Р	Р	Р	P	Р	P	Р	[5,6]
Pediatric	P	Р	Р	Р	Р	P	P	P	Р	P.	[5,6]
Small Organ ^[2]	Р	Р	Р	P	Р	Р	P	Р	P	P	[5,6]
Neonatal Cephalic	P	Р	Р	Р	P	P	P	Р	P	P	[5]
Adult Cephalic	<u> </u>										
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	Р	.р	Р	P	Р	Р	Р	Р	Þ	Р	[5,6]
Musculo-skeletal Conventional	Р	P	Р	P	Р	Р	Р	Р	Р	Р	[5,6]
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral									_		
Intraoperative ⁽⁸⁾											
Intraoperative Neurological											
Intravascular											
Laparoscopic			,								

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) 19/23569

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with RSP6-16-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode of	Operatio	ท			
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes'	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic	<u> </u>	<u> </u>	1								
Fetal/Obstetrics[7]											
Abdominal ^[1]	<u> </u>										
Pediatric	P_	P	Р		· Р	Р	Р	P	Р	Р	[3,5,6]
Small Organ ^[2]	P	Р	Р		Р	P	Р	Р	Р	P	[3,5,6]
Neonatal Cephalic	<u> </u>										
Adult Cephalic											
Cardiac Adult										<u> </u>	
Cardiac Pediatric				,							
Peripheral Vascular	Р_	Р	P		, р	Р	Р	Р	Р	Р	[3,5,6]
Musculo-skeletal Conventional	P	Р	P		Р	Р	P	Р	Р	Р	[3,5,6]
Musculo-skeletal Superficial	P	P	Р		Р	Р	Р	P	P	Р	[3,5,6]
Other ⁽⁴⁾	<u>L</u>						,				
Exam Type, Means of Access		·									
Transesophageal	<u> </u>										
Transrectal											
Transvaginal											
Transurethral			<u> </u>				·				
Intraoperative ^[8]	Р	Р	Р		Р	Р	Р	Р	Р	Р	
Intraoperative Neurological	P	Р	P		P	Р	Р	Р	P	Р	
Intravascular	<u> </u>										
Laparoscopic				•							

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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Office of In Vitro Diagnostics and Radiological Health

510(k) K123564

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with S1-5 Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation PW CW Color Color M Power Combined Harmonic Coded Other											
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]	
Ophthalmic								<u></u>				
Fetal/Obstetrics ⁽⁷⁾	Р	P	P	Р	Р	Р	P	P	P	P	[5,6,9]	
Abdominal ^[1]	P	Р	P_	P	Р	Р	P	Р	Р	Р	[5,6,9]	
Pediatric	P	Р	P	Р	Р	P	P	P	P	P	[5,6,9]	
Small Organ ^[2]												
Neonatal Cephalic												
Adult Cephalic	P	P	Р	Р	Р	Р	P	Р	P	Р	[5,6,9]	
Cardiac Adult	Р	P	Р	Р	Р	P	Р	Р	Φ.	Р		
Cardiac Pediatric												
Peripheral Vascular									•			
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other ^[4]												
Exam Type, Means of Access												
Transesophageal						i.						
Transrectal				·								
Transvaginal ·												
Transurethral											·	
Intraoperative ^[8]											•	
Intraoperative Neurological												
Intravascular												
Laparoscopic												

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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510(k) 18183564

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with S4-10 Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application Anatomy/Region of Interest	В	. м	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]	
Ophthalmic												
Fetal/Obstetrics ⁽⁷⁾	Р	P	Р	P	Р	P	P	P	Р	P	[5,6,9]	
Abdominal ^[1]	Р	P	Р	Р	Р	P	Р	Р	ρ	Р	[5,6,9]	
Pediatric	Р	Р	P	Р	Р	P	Р	. Р	P	Р	[5,6,9]	
Small Organ ^[2]	P	Р	Р	Р	P	Р	Р	Р	P	Р	[5,6,9]	
Neonatal Cephalic	P	Р	Р	Р	Р	P	Р	Р	P	P	[5,6,9]	
Adult Cephalic	<u> </u>											
Cardiac Adult												
Cardiac Pediatric	Р	Р	Р	P	Р	P	P	Р	Р	Р		
Peripheral Vascular	<u></u>					•						
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other ^[4]												
Exam Type, Means of Access												
Transesophageal	<u> </u>											
Transrectal												
Transvaginal												
Transurethral												
Intraoperative ⁽⁸⁾												
Intraoperative Neurological	,										·	
Intravascular												
Laparoscopic												

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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510(k) K123564

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with S4-10-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal/Obstetrics ⁽⁷⁾	E	E	E	E	E	E	E	E	E	Е	[5,6,9]
Abdominal ⁽¹⁾	E	·E	E	<u> </u>	E	E	E	E	E	Е	[5,6,9]
Pediatric	E	E	Е	E	E	E	E	E	E	E	[5,6,9]
Small Organ ^[2]	E	E	E	E	E	E	E	E	E	E	[5,6,9]
Neonatal Cephalic	E	E	E	E	E	E	E	E	E	Е	[5,6,9]
Adult Cephalic	<u> </u>										
Cardiac Adult											
Cardiac Pediatric	E	E	E	E	E	E	E	E	E	Ε	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]										Ll	
Exam Type, Means of Access								:			
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular								,			
Laparoscopic			,								

N = new indication; P = previously cleared by FDA; E = added under Appendix E (previously cleared K111582)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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510(k) 5/23,564

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with C2-9-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application Anatomy/Region of Interest	В	м	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other [Notes]	
Ophthalmic												
Fetal/Obstetrics[7]	E	E	E	€.	E	E	E	E	E	E	[5,6,9]	
Abdominal ^[1]	E	E	E	E	E	E	Ε	E	E	E	[3,5,6,9]	
Pediatric	E	E	E	E	E	E	E	E	E	E.	[3,5,6,9]	
Small Organ ^[2]												
Neonatal Cephalic												
Adult Cephalic				,								
Cardiac Adult	<u> </u>											
Cardiac Pediatric												
Peripheral Vascular	E	E	E	E	E	E	E	E	E	E	[3,5,6,9]	
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Other ^[4]	E	E	E	E	E	Ε'	E	E	E	E	[3,5,6,9]	
Exam Type, Means of Access				-								
Transesophageal												
Transrectal			ļ									
Transvaginal	<u></u>		_									
Transurethral												
Intraoperative ^[8]	<u> </u>											
Intraoperative Neurological												
Intravascular												
Laparoscopic												

N = new indication; P = previously cleared by FDA; E = added under Appendix E (previously cleared K122515)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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Office of In Vitro Diagnostics and Radiological Health

510(h) K.123564

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with RAB6-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]	
Ophthalmic	<u> </u>											
Fetal/Obstetrics[7]	E	Е	E		E	E	Ε	E	E	E	[5,6]	
Abdominal ^[1]	E	E	E		E	E	E	E	E	E	[5,6]	
Pediatric	E	E	E		E	E	E	E	E	E	[5,6]	
Small Organ ^[2]								<u> </u>				
Neonatal Cephalic						***						
Adult Cephalic	ļ <u></u>											
Cardiac Adult												
Cardiac Pediatric	ļ											
Peripheral Vascular	<u> </u>											
Musculo-skeletal Conventional	Ε	E	E		E	E	E	E	E	E	[5,6]	
Musculo-skeletal Superficial												
Other ^[4]	<u> </u>		ļ									
Exam Type, Means of Access			ļ									
Transesophageal												
Transrectal					<u> </u>							
Transvaginal -					<u> </u>					<u> </u>		
Transurethral												
Intraoperative ^[8]												
Intraoperative Neurological			•		<u> </u>							
Intravascular												
Laparoscopic												

N = new indication; P = previously cleared by FDA; E = added under Appendix E (previously cleared K122327)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid .
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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Prescription User (Per 21 CFR 801.109)

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Office of In Vitro Diagnostics and Radiological Health

510M K12356V

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with S1-5-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal/Obstetrics[7]	E	E	E	E	.E	E	E	E	E	E	[5,6,9]
Abdominal ^[1]	E	E	E	E	E	E	E	E	E	Е	[5,6,9]
Pediatric	E	E	Ė	E	E	E	E	E	E	E	[5,6,9]
Small Organ ^[2]											
Neonatal Cephalic											
Adult Cephalic	E	E	E	E	E	E	Ę	E	E	E	[5,6,9]
Cardiac Adult	E	E	Е	E	E	E	E	E	E	E	
Cardiac Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral .											
Intraoperative ^[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Úrology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
- System provides real-time 3D and 4D acquisition when used with special 4D probes

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510(k) K123565

Diagnostic Ultrasound Indications for Use Form GE LOGIQ E9 with C1-6-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application Anatomy/Region of Interest	В	М	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse*	Other [Notes]	
Ophthalmic												
Fetal/Obstetrics ^[7]	Е	Е	E	E	E	E	Е	Е	E	E	[5,6,9]	
Abdominal ^[1]	E	E	E	E	E	E	E	Ē	· E	E	[3,5,6,9]	
Pediatric	E	Е	E	Ε	E	E	E	E	Ė	Ε	[3,5,6,9]	
Small Organ ^[2]												
Neonatal Cephalic												
Adult Cephalic						_						
Cardiac Adult												
Cardiac Pediatric												
Peripheral Vascular	E	E	E	E	E	E	E	E	E	E	[3,5,6,9]	
Musculo-skeletal Conventional	<u> </u>											
Musculo-skeletal Superficial]											
Other ^[4]	E	Е	E	E	E	E	E	E	E	E	[3,5,6,9]	
Exam Type, Means of Access												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral				• •								
Intraoperative ^[8]												
Intraoperative Neurological												
Intravascular			<u> </u>									
Laparoscopic												

N = new indication; P = previously cleared by FDA; E = added under Appendix E (previously cleared K122921)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.

- [2] Small organ includes breast, testes and thyroid
- [3] Elastography Imaging Elasticity.
- [4] Other use includes Urology/Prostate
- [5] 3D/4D Imaging mode
- [6] Needle guidance imaging
- [7] Includes infertility monitoring of follicle development
- [8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
- [9] Volume navigation
- [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

System provides real-time 3D and 4D acquisition when used with special 4D probes

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